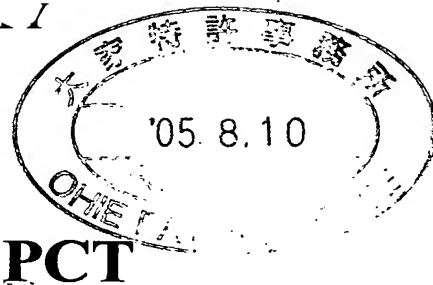


PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY



To:
Mr. OHIE Kunihiisa

OHIE PATENT OFFICE,
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY
(PCT Rule 43bis.1)

Date of mailing
(day/month/year) **09. 8. 2005**

Applicant's or agent's file reference
IHF-5387PCT

FOR FURTHER ACTION

See paragraph 2 below

International application No.
PCT/JP2005/008470

International filing date (day/month/year)
27.04.2005

Priority date (day/month/year)
28.04.2004

International Patent Classification (IPC) or both national classification and IPC
Int.Cl.⁷ A61L27/00

Applicant
IHARA & COMPANY LTD.

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Date of completion of this opinion **26.07.2005**

Name and mailing address of the ISA/JP

Japan Patent Office

3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan

Authorized officer

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4C 9261

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.

PCT/JP2005/008470

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ This opinion has been established on the basis of a translation from the original language into the following language _____, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).

2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
☐ table(s) related to the sequence listing

b. format of material

- ☐ in written format
☐ in computer readable form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/JP2005/008470

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims	<u>2, 8</u>	YES
	Claims	<u>1, 3-7, 9-22</u>	NO
Inventive step (IS)	Claims	<u></u>	YES
	Claims	<u>1-22</u>	NO
Industrial applicability (IA)	Claims	<u>1-22</u>	YES
	Claims	<u></u>	NO

2. Citations and explanations

D1:JP 01-230365 A (Terumo Corp., Japan)

D2:JP 2003-534858 A(Coletica, Fr.)

D1 discloses the method of manufacturing a collagen material including a step in which gel comprising collagen fiber cross-linked by using a water-soluble carbodiimide is subjected to a thermal treatment (claims 1-4; page 6 lines 16-18; page 8, lines 1-4).

D1 also describes that solvent inducing fiber formation is an aqueous solution of salt having a buffering ability selected from phosphate (page 7, lines 6-13).

Furthermore, D1 mentions the collagen material manufactured by above mentioned method is used as a cell carrier.

D1 does not concretely mention that the collagen material manufactured by the above mentioned method is stretchable; however, as the stretchable collagen material of claim 1, 3, 4, and 16-22 is also manufactured by the same method as described in D1, the collagen material disclosed in D1 is deemed to be stretchable.

Therefore the subject matter of claims 1, 3-7, and 9-22 seems neither to be novel nor to involve an inventive step.

D2 discloses collagen material derived from fish is useful for implant or artificial tissues in view of safety and amount of sources. Therefore the person skilled in the art would easily apply collagen derived from fish disclosed in D2 instead of collagen derived from livestock in D1, so the subject matter of claims 2 and 8 do not seem to involve an inventive step.